

K090163

PREMARKET NOTIFICATION [510(K)] SUMMARY

Date Prepared: January 21, 2009
Submitter: St. Jude Medical, CRMD
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Contact Person: Geena George
Trade Name/Proprietary Name: SJM Stylet Model Numbers:
4060, 4062, 4064
4090, 4091
4078
Locator Plus
S-60-S, S-60-X, S-60-F
S-65-S, S-65-F, S-65-X
S-75-X, S-75-S, S-75-F
S-60-XS, S-65-XS, S-75-XS

APR - 1 2009

Common Name: Stylet

Classification: Class II, 21 CFR 870.1380

Legally marketed device
to which your firm is
claiming equivalence:

St. Jude Medical stylets under review are all currently
commercially available.

| SJM Stylet Model | Approved with PMA Number |
|------------------------------|--------------------------|
| 4060, 4062 and 4064 | P960030/S10 |
| 4090 and 4091 | P960013/S15 |
| Locator Plus | P960013/S022 |
| S-60-S, S-60-X, S-60-F | P950022/S16 |
| S-65-S, S-65-F, S-65-X | P950022/S14, P950022/S16 |
| S-75-X, S-75-S, S-75-F | P950022/S17 |
| S-60-XS, S-65-XS, S-75-XS | P950022/S34 |

1) Stylet Model 4060, 4062 and 4064

A. Device Description

The Stylet models 4060, 4062, 4064 were reviewed and approved by FDA with the Isoflex S family of leads under P960030/S10 on April 10, 2003. Stylet lengths approved were 34cm, 40cm, 46cm, 52cm, 58cm, 85cm.

Model 4060 is a soft straight stylet 0.35mm (.014'') with green knob.

Model 4062 is a firm straight stylet 0.38mm (0.015'') with yellow knob.

Model 4064 is an extra firm straight stylet 0.41mm (0.016'') with red knob.

The market released Isoflex S specification sheet referencing the stylet models is included as appendix 1

The stylet models 4060, 4062 and 4064 are intended for use in the placement of Isoflex S passive fixation pacing leads. The Isoflex S lead is designed for use to provide permanent pacing and sensing in either the atrium or ventricle.

4060 stylet accessories kit contains:

Two 0.014'' stainless steel stylets with button I.D. designating the length of the stylet:

- 2 Soft stylets with green knob and green button.

4062 stylet accessories kit contains:

Two 0.015'' stainless steel stylets with button I.D. designating the length of the stylet:

- 2 Firm stylets with yellow knob and yellow button

4064 stylet accessories kit contains:

Two 0.016'' stainless steel stylets with button I.D. designating the length of the stylet:

- 2 X-Firm stylets with red knob and red button

A stylet ring is used to hold the stylets. The kits shall be packaged in double trays or in double pouches.

These stylets are available with leads and also as accessories with packaging identical to the packaging under PMA P960030/ S10.

Stylet Testing

Stylet insertion/extraction testing was performed with Isoflex S family of leads per QTR 0210866, section 8.11(attached in appendix 2) and per QTR 02109049, section 8.12 (attached in appendix 3)

Sterilization and Packaging

The stylets are held in a common polymer ring, packaged and sealed within a polymer tray documented as per QTR 1392-A (attached in appendix 4). The stylet kits are sterilized at Steris Isomedix and meets all requirements as per QTR2264 (included as appendix 5)

Shelf Life

The 4060, 4062 and 4064 stylets have a shelf life approved for 3 years for leads packaged with the stylets under PMA P960030/ S10

Labeling

Labels for commercially available stylet models 4060, 4062 and 4064 is included as appendix 6

B. Indications for use

The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices

St Jude Medical believes the stylet kit models 4060, 4062 and 4064 to be substantially equivalent to the predicate stylet models 4060, 4062 and 4064 approved by FDA under the Isoflex S family of leads under P960030/S10 on April 10, 2003.

Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion

The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet models 4060, 4062 and 4064 through this 510K Pre- Market Notification.

2) Stylet Model 4090 and 4091**A. Device Description**

The Stylet Accessory kit models 4090 and 4091 were reviewed and approved by FDA with the Tendril ST lead model 1788T/TC and 1782 TC under P960013/S15 on Feb 7, 2006. Stylet lengths approved were 25cm, 34cm, 40cm, 46cm, 52cm, 58cm, 65cm, 85cm and 100cm. Included in appendix 7 is the information referencing the stylets as discussed with FDA on January 20, 2006.

The stylet models 4090 and 4091 are intended for use in the placement of Tendril ST Model 1788T/TC and Model 1782 TC pacing leads.

These are stainless steel stylets with button I.D. designating the length of the stylet.

Each 4090 stylet accessories kit contains:

- 1 Fixation Tool
- 1 Clip-on Tool
- 1 J-shaped Soft (.014" wire) stylets with green knob and white button
- 1 Straight X-Soft (.014" wire) stylets with light green knob and green button
- 1 Straight Soft (.014" wire) stylets with green knob and green button.
- 1 Straight Firm (.015" wire) stylets with yellow knob and yellow button

- 1 Straight X–Firm (.016” wire) stylets with red knob and red button

Each 4091 stylet accessories kit contains

- 1 Clip–on Tool
- 1 J–shaped Soft (.014” wire) stylet with green knob and white button.
- 1 Straight X–Soft (.014” wire) stylets with light green knob and green button.
- 1 Straight Soft (.014” wire) stylets with green knob and green button.
- 1 Straight Firm (.015” wire) stylets with yellow knob and yellow button.
- 1 Straight X–Firm (.016” wire) stylets with red knob and red button.

A stylet ring is used to hold these stylets.

The 4090 kit with pre–packaged Fixation Tool and Clip–on Tool shall be packaged in double pouches. The 4091 kit with clip-on tool shall be packaged in double pouches.

Stylet Testing

Description of the stylet kit model 4090 & 4091 as well as the qualification testing on the 4090, 4091 stylets kit models was performed per QTR 1861 and had previously been submitted as part of the 1788/1782 RTR submission. This QTR 1861 is included as appendix 8

Sterilization & Packaging

The stylets and accessory Kit 4090 and 4091 sterilization and packaging validation was performed per QTR 1861 and is included in Appendix 8.

Shelf Life

The 4090 and 4091 stylet have a shelf life approved for 3 years for leads packaged with the stylets under P960013/S15.

Labeling

Labels for commercially available stylet model 4090 and 4091 are included as appendix 9.

B. Indications for use

The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices

St Jude Medical believes the stylet kit models 4090 and 4091 to be substantially equivalent to the predicate stylet models 4090 and 4091 approved by FDA under the Tendril ST lead model 1788T/TC and 1782 TC under P960013/S15 on Feb 7, 2006. Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion

The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet kit models 4090 and 4091 through this 510K Pre- Market Notification.

3) Stylet Model 4078S**A. Device Description**

Stylet kit 4078S was approved under PMA P030054/S49 with Quickflex Model 1156T and Quickflex XL Model 1158T on July 25, 2007. The Quickflex Model 1156T and Quickflex XL Model 1158T leads have applications as part of a St Jude Medical Biventricular system. Stylet lengths approved were 75cm and 86 cm.

The 4078 stylet is constructed of stainless steel. Stylet accessory kit (Model 4078S) consisting of a fully packaged and labeled set of six ball-tipped stylets.

- One Extra firm stylet with 0.025 cm (0.010'') taper (red button)
- Two Firm stylets with 0.020 cm (0.008'') taper (yellow button)
- Three Soft stylets with .015 cm (.006'') taper (green button)

A stylet ring is used to hold the stylets. The 4078 kits shall be packaged in a single pouch.

Stylet Testing

Stylet insertion/extraction testing was performed per QTR 2019 for 1156T Quickflex leads and per QTR 2020 for 1158T Quickflex leads attached in Appendix 10.

Sterilization and Packaging

The stylets kit 4078 sterilization and packaging validation was not required. Sterilization and packaging validation performed on the 4068 stylet kit per QTR 1511 is applicable and is included in appendix 11.

Shelf Life

The 4078 stylet has a shelf life approved for 3 years for leads packaged with the stylets under P030054/S49

Labeling

Labels for commercially available stylet model 4078 are included as appendix 12.

B. Indications for use

The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices

St Jude Medical believes the stylet model 4078 to be substantially equivalent to the predicate stylet model 4078 approved by FDA under PMA P030054 with Quickflex Model 1156T and Quickflex XL Model 1158T on Feb 5, 2007.

Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion

The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet model 4078 through this 510K Pre-Market Notification.

4) Locator Plus Stylets**Device Description**

Locator plus deflectable stylets 1281, 1282, 1283, 1291, 1292, 1293 were approved under PMA P960013/S022 on October 10, 2006. The lengths approved are 42cm, 56cm, 65cm and 58cm.

The Locator plus RTR submission is included as appendix 13. The FDA approval letter for the Locator plus RTR is provided in Appendix 14.

Locator plus deflectable stylet is a disposable implantation tool which facilitates defining and varying the curvature of the distal portion of an endocardial pacing lead, as well as controlling the lead's helix extension and retraction during lead insertion.

The stylet package contains

- 1 Locator® Plus Deflectable Stylet.
- 1 Protection tube with plastic stop attached to the tube.
- 1 Transport protection attached to the Stylet.
- 1 User's Manual.

The product is double-packaged in PETG inner and outer trays with tyvek seals to maintain sterility.

Shelf Life

The Locator plus stylet has a shelf life approved for 2 years under P960013/S022.

B. Indications for use

The locator Plus Deflectable stylet is intended for use when implanting St Jude Medical active fixation straight endocardial pacemaker leads, Tendril[®] Model 1688 SDX and higher.

C. Substantially Equivalent Devices

St Jude Medical believes the Locator Plus Deflectable stylet to be substantially equivalent to the predicate Locator Plus Deflectable stylet approved by FDA under PMA P960013/S022 on October 10, 2006.

D. Conclusion

The information presented supports a determination of substantial equivalence and therefore clearance of the SJM Locator Plus Deflectable stylet through this 510K Pre- Market Notification.

5) Stylet Model S-65-S, S-65-F, S-65-X**A. Device Description**

These stylet accessory kits support the Riata Model 1500 family of leads. They were approved under PMA P950022/S14 on March 11, 2002 and PMA P950022/S16 on March 25, 2003.

The market released leads specification sheet referencing the stylet models is included as appendix 15

These stylets are used with Tachyarrhythmia leads. All stylets are constructed of 304 stainless steel and a molded ABS thermoplastic hub that is colored red, yellow, green to identify between extra firm, firm and soft. The soft stylet S-65-S has a 0.014 inch diameter, the firm stylet S-65-F has a 0.015 inch diameter and the extra firm stylet S-65-X has a 0.016 inch diameter.

Each S-65-S kit contains (1) clip on tool and the following stylets

- 2 soft(0.014''wire) ball tipped, stylets with green knob

Each S-65-F kit contains (1) clip on tool and the following stylets

- 2 firm(0.015''wire) ball tipped, stylets with yellow knob

Each S-65-X kit contains (1) clip on tool and the following stylets

- 2 extra firm(0.016''wire) ball tipped, stylets with red knob

A stylet ring holder is used to hold the stylets. The kit shall be packaged in double trays or in double pouches. The final sterile package shall be packaged in a poly bag.

Stylet Testing

Stylet insertion extraction test was conducted as per Qualification Test Report QTR1403 attached in appendix 16.

Sterilization and Packaging

These stylets are packaged with the Riata and Durata family of leads. Sterilization and packaging validation was performed per QTR 2264 and is included in appendix 5.

Shelf Life

These stylets have a shelf life approved for 3 years for leads packaged with the stylets under P950022/S14 and P950022/S16

Labeling

Labels for commercially available stylet model S-65-S, S-65-F, S-65-X are included as appendix 17.

B. Indications for use

The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices

St Jude Medical believes the stylet models S-65-S, S-65-F, S-65-X to be substantially equivalent to the predicate stylet model S-65-S, S-65-F, S-65-X approved by FDA under PMA P950022/S14 on March 11, 2002 and PMA P950022/S16 on March 25, 2003 with Riata Model 1500 family of leads. Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion

The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylets S-65-S, S-65-F, S-65-X through this 510K Pre- Market Notification.

6) Stylet Model S-60-S, S-60-X, S-60-F

A. Device Description

These stylet models are developed to support the Riata defibrillation lead models 1572 and 1582. They were approved under PMA P950022/S16 on March 25, 2003.

The market released lead model 1572 and model 1582 specification sheet referencing the stylet models is included as appendix 18.

These stylets are used with Tachyarrhythmia leads. All stylets are constructed of 304 stainless steel and a molded ABS thermoplastic hub that is colored red, yellow, and green to identify between extra firm, firm and soft. The soft stylet S-60-S has a 0.014 inch diameter, the firm stylet S-60-F has a 0.015 inch diameter and the extra firm stylet S-60-X has a 0.016 inch diameter.

Each S-60-S kit contains (1) clip on tool and the following stylets

- 2 soft(0.014''wire) ball tipped, stylets with green knob

Each S-60-F kit contains (1) clip on tool and the following stylets

- 2 firm(0.015''wire) ball tipped, stylets with yellow knob

Each S-60-X kit contains (1) clip on tool and the following stylets

- 2 extra firm(0.016''wire) ball tipped, stylets with red knob

A stylet ring holder is used to hold the stylets. The kit shall be packaged in double trays or in double pouches. The final sterile package shall be packaged in a poly bag.

Stylet Testing

Stylet insertion extraction test was conducted per qualification test report QTR1472 for Riata Model 1572 attached in appendix 19 and QTR1462 for Riata Model 1582 lead attached in appendix 20 .

Sterilization and Packaging.

These stylets are packaged with the Riata and Durata family of leads. Sterilization and packaging validation was performed per QTR 2264 and is included in appendix 5.

Shelf Life

These stylets have a shelf life approved for 3 years for leads packaged with the stylets under P950022/S16.

Labeling

Labels for commercially available stylet model S-60-S, S-60-X, S-60-F are included as appendix 21.

B. Indications for use

The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices

St Jude Medical believes the stylet models S-60-S, S-60-F, S-60-X to be substantially equivalent to the predicate stylet model S-60-S, S-60-F, S-60-X approved by FDA under PMA P950022/S16 on March 25, 2003 with Riata defibrillation lead models 1572 and 1582.

Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion

The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet S-60-S, S-60-F, S-60-X through this 510K Pre- Market Notification.

7) Stylet Model S-75-X, S-75-S, S-75-F

A. Device Description

Stylet Models S-75-X, S-75-S and S-75-F were approved under PMA P950022/S17 on July 1, 2003. The market released lead models 1580, 1581 and 1582 specification sheet referencing the stylet models is included as appendix 22.

These stylets are used with Tachyarrhythmia leads. All stylets are constructed of 304 stainless steel and a molded ABS thermoplastic hub that is colored red, yellow, and green to identify between extra firm, firm and soft. The soft stylet S-75-S has a 0.014 inch diameter, the firm stylet S-75-F has a 0.015 inch diameter and the extra firm stylet S-75-X has a 0.016 inch diameter.

Each S-75-S kit contains (1) clip on tool and the following stylets

- 2 soft(0.014''wire) ball tipped, stylets with green knob

Each S-75-F kit contains (1) clip on tool and the following stylets

- 2 firm(0.015''wire) ball tipped, stylets with yellow knob

Each S-75-X kit contains (1) clip on tool and the following stylets

- 2 extra firm(0.016''wire) ball tipped, stylets with red knob

A stylet ring holder is used to hold the stylets. The kit shall be packaged in double trays or in double pouches. The final sterile package shall be packaged in a poly bag.

Stylet Testing

Stylet insertion extraction test was performed and validated as per QTR 1606 for the Riata model 1580/1581 attached in appendix 23.

Sterilization and Packaging.

These stylets are packaged with the Riata/Durata leads. Sterilization and packaging validation was performed per QTR 2264 and is included in appendix 5.

Shelf Life

These stylets have a shelf life approved for 3 years for leads packaged with stylets under P950022/S17.

Labeling

Labels for commercially available stylet models S-75-X, S-75-S, S-75-F are included as appendix 24.

B. Indications for use

The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices

St Jude Medical believes the stylet models S-75-X, S-75-S, S-75-F to be substantially equivalent to the predicate stylet model S-75-X, S-75-S, S-75-F approved by FDA under PMA P950022/S17 on July 1, 2003 with Riata lead models 1580, 1581 and 1582.

Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion

The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet S-75-X, S-75-S, S-75-F through this 510K Pre- Market Notification.

8) Stylet model S-60-XS, S-65- XS, S-75-XS

A. Device Description

These stylet models were approved under PMA P950022/S34 on March 8, 2007. These stylet accessory kits include the existing extra firm, firm, soft stylets with the addition of the extra soft stylet. The extra soft stylet models (S-60-XS, S-65-XS, S-75-XS) have the same material properties as the existing soft stylets. The differences are due to the variation in the taper length and taper diameter at the tip, which provides for a more flexible or extra soft distal end. The extra soft stylets were approved under P950022/S34 on March 8, 2007. The information detailing the extra soft stylets as discussed with FDA on January 29, 2007 is included as appendix 25.

These stylets are used with Tachyarrhythmia leads. The extra soft stylets are light green in color.

Each stylet kit contains (1) clip-on tool and the following stylets:

- 2 Straight X-Soft (.014" wire) ball-tipped, stylets with light green knob

A stylet ring is used to hold the stylets.

The kits with Clip-on Tool shall be packaged in double pouches.

Stylet Testing

Stylet insertion extraction test was conducted as per qualification report QTR 2041 and is attached in appendix 26.

Sterilization and Packaging

The extra soft stylets are inserted into the Riata lead when packaged Sterilization and packaging validation performed per QTR 1392-G is included in appendix 27.

Shelf Life

These stylets have a shelf life approved for 3 years for leads packaged with stylets under P950022/S34.

Labeling

Labels for commercially available stylet model S-60-XS, S-65-XS, S-75-XS are included as appendix 28.

B. Indications for use

The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

C. Substantially Equivalent Devices

St Jude Medical believes the stylet models S-60-XS, S-65- XS, S-75-XS to be substantially equivalent to the predicate stylet model S-60-XS, S-65- XS, S-75-XS approved by FDA under PMA P950022/S34 on March 8, 2007 .

Labeling, packaging and sterilization of the stylets is substantially equivalent to that of the predicate stylets.

D. Conclusion

The information presented supports a determination of substantial equivalence and therefore clearance of the SJM stylet S-60-XS, S-65- XS, S-75-XS through this 510K Pre- Market Notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2009

St. Jude Medical
Cardiac Rhythm Management Division
Geena George
Regulatory Affairs Associate
15900 Valley View Court
Sylmar, California 91342

Re: K090163

Trade/Device Names:

Stylet Models 4060, 4062, 4064
Stylet Models 4090, 4091 Accessory Kit
Stylet Model 4078
Locator Plus Stylets 1281, 1282, 1283, 1291, 1292, 1293
Stylet Model S-60-S, S-60-F, S-60-X
Stylet Model S-65-S, S-65-F, S-65-X
Stylet Model S-75-S, S-75-F, S-75-X
Stylet Model S-60-XS, S-65-XS, S-75-XS

Regulation Number: 21 CFR 870.1380

Regulation Name: Catheter stylet

Regulatory Class: Class II

Product Code: DRB

Dated: January 21, 2009

Received: January 22, 2009

Dear Ms. George:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

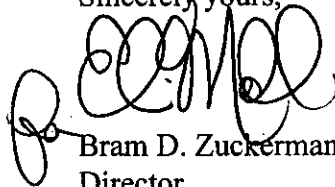
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K090163


Device Name: St Jude Medical Stylet Model Numbers:
4060, 4062, 4064
4090, 4091
4078
Locator Plus
S-60-S, S-60-X, S-60-F
S-65-S, S-65-F, S-65-X
S-75-X, S-75-S, S-75-F
S-60-XS, S-65-XS, S-75-XS

Indications for Use: The stylet is intended to aid in the placement of St. Jude Medical transvenous leads.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090163